INITIAL APPROVAL: JULY 11, 2018
REVISED DATES: APRIL 8, 2020
OCTOBER 9, 2019;
JULY 10, 2019;
OCTOBER 10, 2018

CRITERIA FOR PRIOR AUTHORIZATION

Antidepressant Medications – Safe Use for All Ages

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available of the medications below:

Amitriptyline (Elavil®)
Amoxapine
Bupropion (Forfivo® XL, Wellbutrin®, Wellbutrin® SR, Wellbutrin® XL)
Citalopram (Celexa®)
Clomipramine (Anafranil®)
Desipramine (Norpramin®)
Desvenlafaxine (Khedezla®, Pristiq®)
Doxepin (Sinequan®)
Duloxetine (Cymbalta®, Drizalma Sprinkle™)
Escitalopram (Lexapro®)
Esketamine (Spravato®)
Fluoxetine (Prozac®, Prozac Weekly®)
Fluvoxamine (Luvox®, Luvox CR®)
Imipramine (Tofranil®, Tofranil® PM)
Isocarboxazid (Marplan®)
Levomilnacipran (Fetzima®)
Maprotiline
Milnacipran (Savella®)
Nefazodone
Nortriptyline (Pamelor®)
Olanzapine/Fluoxetine (Symbyax®)
Paroxetine (Paxil®, Paxil CR®, Pexeva®)
Phenelzine (Nardil®)
Protriptyline (Vivactil®)
Selegiline (Emsam®)
Sertraline (Zoloft®)
Tranylcypromine (Parnate®)
Trimipramine (Surmontil®)
Venlafaxine (Effexor®, Effexor XR®)
Vilazodone (Viibryd®)
Vortioxetine (Trintellix®)

CRITERIA FOR PRIOR AUTHORIZATION FOR ANTIDEPRESSANTS MEDICATIONS:

- For all agents listed, the preferred PDL drug, if applicable, which covers this indication, is required unless the patient meets the non-preferred PDL PA criteria.

- MULTIPLE CONCURRENT USE:
  - Each of the following criteria for multiple concurrent use will require prior authorization:
    - For patients **< 13 years of age**, two or more different antidepressants used concurrently for greater than 60 days
    - For patients **≥ 13 years of age**, three or more different antidepressants used concurrently for greater than 60 days
    - Two or more different selective serotonin reuptake inhibitors (SSRIs) used concurrently for greater than 60 days (defined in table 1)
    - Two or more different serotonin norepinephrine reuptake inhibitors (SNRIs) used concurrently for greater than 60 days (defined in table 2)
    - Two or more different tricyclic antidepressants (TCAs) used concurrently for greater than 60 days (defined in table 3)

DRAFT PA Criteria

- Prior authorization will require written peer-to-peer consult with health plan psychiatrist, medical director, or pharmacy director for approval, followed by a verbal peer-to-peer if unable to approve written request.

LENGTH OF APPROVAL: 12 months

RENEWAL CRITERIA: Patient is stable and has been seen in the past year.

CRITERIA FOR PRIOR AUTHORIZATION FOR ESKETAMINE (SPRAVATO™) NASAL SPRAY:

- Age ≥ 18 years of age.[4,7]
- Patient must have a diagnosis of treatment-resistant depression, including ALL of the following:
  - DSM-5 criteria for major depressive disorder.
  - Inadequate response (in the current episode) to at least ~~2~~ 3 different antidepressants (listed in Tables 1-4) despite therapeutic dose and 6 weeks[1] duration of each medication.
- ~~Patient must be started on a new oral antidepressant in conjunction with esketamine.~~ Patient must be maintained on antidepressant(s) while on therapy with Spravato.
- Patient must have an adequate trial (at least 4 weeks) of at least ONE of the following augmentation therapies, or a contraindication to all therapies listed in Table 5:[1]
  - Addition of a second-generation antipsychotic listed in Table 5 to the current regimen.
  - Addition or change in medication therapy to a fixed-dose combination product of olanzapine/fluoxetine.
- Prescriber must provide baseline Montgomery-Asberg Depression Rating Scale (MADRS) or Hamilton Depression scale (HAM-D) or Patient Health Questionnaire (PHQ-9) before initial treatment with intranasal esketamine.
  - Patient must have severe depression as defined by MADRS or HAM-D or the PHQ-9. See Table 6 below.
- ~~Prescriber must provide baseline Patient Health Questionnaire (PHQ-9) before initial treatment AND at each subsequent visit for the treatment with intranasal esketamine. (only if the prescriber intends to monitor treatment response with the PHQ-9).[6]~~
- Patient, provider, and provider's staff must be registered, educated, and be in good standing with the associated REMS program.
- Dose does not exceed 168mg (6 nasal spray devices) per week for induction (initial 4 weeks).[4,7]
- Dose does not exceed 84mg (3 nasal spray devices) per week for maintenance (beyond initial 4 weeks).[4,7]
- Patient must be screened for active/risk for substance use disorder.
- Prescriber has addressed the appropriateness of psychotherapy with the patient.

LENGTH OF INITIAL APPROVAL: 6 months

RENEWAL CRITERIA:

- Prescriber must provide the following response measure(s).
  - Stable response was maintained, defined as MADRS or HAM-D or PHQ-9 average decrease ≥50% from baseline, with a minimum of 3 assessments with the same tool. ~~, for the majority of the assessments since the most recent approval.~~
- Patient has < 2 relapses since the most recent approval. A relapse is defined as hospitalization or overnight observation for worsening depression.
- Patient must be screened for active/risk for substance use disorder.
- Dose does not exceed 84mg (3 nasal spray devices) per week for maintenance.[4,7]

LENGTH OF APPROVAL FOR RENEWAL: 12 months

DRAFT PA Criteria

TABLE 1. SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRIS)

SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRIS)
Citalopram (Celexa®)
Escitalopram (Lexapro®)
Fluoxetine (Prozac®, Prozac Weekly®)
Fluvoxamine (Luvox®, Luvox CR®)
Paroxetine (Paxil®, Paxil CR®, Pexeva®)
Sertraline (Zoloft®)
Vilazodone (Viibryd®)*
Vortioxetine (Trintellix®)**

*Vilazodone also has partial agonistic 5-HT_{1A} activity
**Vortioxetine also has agonistic 5-HT_{1A} and antagonistic 5-HT_3 activity

TABLE 2. SEROTONIN-NOREPINEPHRINE REUPTAKE INHIBITORS (SNRIS)

SEROTONIN-NOREPINEPHRINE REUPTAKE INHIBITORS (SNRIS)
Desvenlafaxine (Khedezla®, Pristiq®)
Duloxetine (Cymbalta®, Drizalma Sprinkle™)
Levomilnacipran (Fetzima®)
Milnacipran (Savella®)
Venlafaxine (Effexor®, Effexor XR®)

TABLE 3. TRICYCLIC ANTIDEPRESSANTS (TCAS)

TRICYCLIC ANTIDEPRESSANTS (TCAS)
Amitriptyline (Elavil®)
Amoxapine
Clomipramine (Anafranil®)
Desipramine (Norpramin®)
Doxepin (Sinequan®)
Imipramine (Tofranil®)
Imipramine Pamoate (Tofranil® PM)
Nortriptyline (Pamelor®)
Protriptyline (Vivactil®)
Trimipramine (Surmontil®)
TETRACYCLIC ANTIDEPRESSANTS
Maprotiline

TABLE 4. OTHER ANTIDEPRESSANTS

DOPAMINE NOREPINEPHRINE REUPTAKE INHIBITORS
Bupropion (Forfivo® XL, Wellbutrin®, Wellbutrin® SR, Wellbutrin® XL)
SEROTONIN MODULATORS
Nefazodone (Serzone)
Monoamine Oxidase Inhibitors (MAOIs)
Phenelzine (Nardil®)
Tranylcypromine (Parnate®)
Isocarboxazid (Marplan)
Selegiline transdermal system (Emsam®)

DRAFT PA Criteria

TABLE 5. AUGMENTATION THERAPIES[1,5-8,8-11]

SECOND-GENERATION ANTI-PSYCHOTICS (SGAs)
Aripiprazole (Abilify®)
Brexpiprazole (Rexulti®)
Olanzapine/fluoxetine (Symbyax®) (fixed combination product)
Quetiapine Extended Release (Seroquel XR®)

TABLE 6. CUTOFFS FOR SEVERE DEPRESSION[3-4]

RATING SCALE	CUTOFF SCORE FOR SEVERE DEPRESSION
MADRS	≥ 35
HAM-D	≥ 19
PHQ-9	≥ 20

Notes:

- Mirtazapine, and trazodone are FDA-indicated for depression, but are not listed because they are primarily used for other indications.

References:

1. Practice Guideline for the Treatment of Patients with Major Depressive Disorder, Third Edition. American Psychiatric Association, October 2010. Available at https://psychiatryonline.org/guidelines. Accessed 7/24/19.
2. Psychotropic Medication Utilization Parameters for Children and Youth In ~~Foster Care~~Texas Public Behavioral Health (~~5th~~-6th Version). ~~Texas Department of Family and Protective Services and The University of Texas at Austin College of Pharmacy~~The Parameters Workgroup of the Psychiatric Executive Formulary Committee, Health and Specialty Care Division, Texas Health and Human Services Commission, ~~March 2016~~ June 2019~~(updated July 2016)~~. Available at https://www.dfps.state.tx.us/Child_Protection/Medical_Services/Psychotropic_Medications.asp~~http://texaschildrenscommission.gov/reports-and-resources/~~. Accessed ~~8/6/19~~10/23/19.
2. ~~
3. Maust, D, Cristancho M, et al. Chapter 13 – Psychiatric rating scales. Neurobiology of Psychiatric Disorders. Handbook of Clinical Neurology, 2012. Available at . Accessed 7/23/19.~~
3. Grade Scores of the Montgomery-Asberg Depression and the Clinical Anxiety Scales. Br J Psychiatry 1986; 148:599-601. Available at https://www.cambridge.org/core/journals/the-british-journal-of-psychiatry/article/grade-scores-of-the-montgomeryasberg-depression-and-the-clinical-anxiety-scales/E03CC2A39EEE29F47DAAE56A48B4EA60. Accessed 9/17/19.
4. Severity classification on the Hamilton depression rating scale. J Affect Disord 2013; 150(2):384-8. Available at https://www.sciencedirect.com/science/article/abs/pii/S0165032713003017?via%3Dihub. Accessed on 9/17/19.
5. Patient Health Questionnaire (PHQ9). Available at https://www.integration.samhsa.gov/clinical-practice/screening-tools. Accessed 10/21/19.
6. Zimmerman, M. Using the 9-item Patient Health Questionnaire to Screen for and Monitor Depression. JAMA October 2019. [Epub ahead of print]. Available at https://jamanetwork.com/journals/jama/article-abstract/2753532. Accessed on 10/22/19.
4.7. Spravato (esketamine) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; May 2019.
5.8. Abilify (aripiprazole) [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; February 2017.
6.9. Rexulti (brexipiprazole) [package insert]. Otsuka America Pharmaceutical, Inc.; February 2018.
7.10. Symbyax (olanzapine/fluoxetine) [package insert]. Indianapolis, IN: Lilly USA, LLC; March 2018.
8.11. Seroquel XR (quetiapine) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2018.

_____

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

_____

DATE

_____

PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

_____

DATE